IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE GENERAL-CAUSATION TESTIMONY OF DIONYSIOS K. VERONIKIS, M.D.

Dionysios K. Veronikis, M.D., seeks to offer various opinions regarding the ability of the TVT and Gynemesh PS mesh products to cause the injuries alleged by several plaintiffs in this litigation. Certain of these opinions are inadmissible under this Court's own rulings, Rules 702 and 403, and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). These opinions include:

- **Opinions as to what an adequate IFU should have contained**. Dr. Veronikis's opinion is premised on what he claims Ethicon knew based on his review of company documents. This is not a reliable methodology for forming warnings-adequacy opinions.

- **Opinion that TVT mesh is not suitable for its intended application because it degrades, frays, and experiences particle loss.** Dr. Veronikis criticizes TVT mesh as prone to fraying, falling apart, and degrading within the body, yet he relies on internal company documents as to what Ethicon knew as the basis for that opinion. This opinion is not the product of a reliable methodology.

- **Opinion that TVT mesh is defectively designed because Ethicon's recommended surgical technique is unsafe.** A surgical technique is not a product. To the extent that Dr. Veronikis criticizes the surgical technique for implanting the TVT, that opinion is inadmissible to prove a design defect.

- **Opinion that all mesh is unsafe for vaginal use**. Dr. Veronikis's opinion that all polypropylene mesh products are unsafe for treating stress urinary incontinence (SUI) is belied by his admission that he uses polypropylene mesh as part of his clinical practice.

- **Opinion that Pronova is a safer alternative to Gynemesh PS**. Dr. Veronikis admits that Pronova, which he believes is a safer alternative mesh design, is not available as an alternative product for prolapse repair. This product therefore cannot serve as a feasible alternative to prove design defect.

- **Opinions that Ethicon failed to adequately warn physicians and that TVT and Gynemesh PS are defectively designed because they are not reasonably safe for their intended uses.** These are legal conclusions that are within the province of the jury, not an expert witness.

- **Opinions relating to Ethicon's motive, knowledge, and intent.** This Court has repeatedly excluded this type of opinion testimony in other cases.

ARGUMENTS AND AUTHORITIES

Ethicon incorporates by reference the standard of review for *Daubert* motions articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014).

I. Dr. Veronikis's Warnings Opinions Are Unreliable and Should Be Excluded Because They Are Based on Corporate Knowledge, Conduct, or Motives.

Dr. Veronikis offers several warnings opinions with respect to both TVT and Gynemesh PS, which are premised on nothing more than his review and regurgitation of Ethicon company documents that he claims show what Ethicon knew or how Ethicon conducted itself. Ex. C, Veronikis TVT Report at 10-14; Ex. D, Veronikis Gynemesh PS Report at 5-15. These opinions include, among others:

- Opinions based on communications from Meng Chen "explain[ing] to Ethicon['s] upper management '. . . the current knowledge of the manufacturers'" (Ex. C, Veronikis TVT Report at 11);

- Opinions based on communication from Dr. Aaron Kirkemo explaining "we have 12+ years of experience with TVT classic that learnings from the field would probably drive a relook at the TVT Classic IFU" (*id.*);

- Opinion that "[t]he TVT IFU contains several statements that . . . are misleading because they contradict information known or at least available to Ethicon, according to Ethicon['s] own documents" (*id.* at 12);

- Opinions claiming that "Ethicon['s] internal documents reflect that the polypropylene material used in the TVT mesh was subject to degradation inside the body" and "that the polypropylene material . . . causes an 'excessive' and 'chronic' foreign body reaction and 'intense' and 'chronic' inflammation" (*id.*);

- Opinions that Ethicon knew of "numerous serious safety risks associated with the TVT that have never been included in the TVT IFU" (*id.*);

- Opinions that Ethicon's "internal documents and employees acknowledge" they knew that the "minimum pore size of mesh must be greater than 1 mm after implantation" (*id.* at 13);

- Opinions based on Ethicon internal document reflecting "concern that 'overinformation' about mesh removal would be 'digging my own grave'" (*id.* at 14);

- Opinion that "Ethicon corporate documents . . . demonstrate[e] that they had knowledge that the mesh material used in construction of Gynemesh PS elicits an 'excessive' and 'chronic' foreign body reaction and 'intense' and 'chronic' inflammation" (Ex. D, Veronikis Gynemesh PS Report at 5-6);

- Opinions based on an internal email chain stating that "[Ethicon employees] 'know from literature that polyester and even polypropylene tend to alter over time in the body'" (*id.* at 6);

- Opinions based on "[n]umerous other Ethicon documents discuss[ing] their knowledge of the material being stiff and inflexible, as well as over-engineered, too strong and not designed for the pelvic floor" (*id.* at 7);

- Opinions stating that Ethicon had "knowledge from a clinical study conducted by Michel Cosson" that showed "Gynemesh PS was 'better suited' for patients with severe Pelvic Organ Prolapse" (*id.* at 9-10);

- Opinions that Ethicon knew from "an internal e-mail regarding the Prolene Soft pore size" that "'pore size measurements vary if the mesh is pulled even lightly in any direction'" (*id.* at 10);

- Opinions based that internal Ethicon e-mails that the company was "concern[ed]" over mesh shrinkage and "acknowledge[ed] . . . the need to improve the Prolene Soft/Gynemesh PS" products (*id.* at 10-11);

- Opinions based on communications from Ethicon's European Medical Director encouraging the use of additional warnings about mesh erosion and retraction in the Prolift IFU (*id.* at 11);

- Opinion that Ethicon "had knowledge that the arms on the Prolift device . . . deform and 'crumple' during implantation" (*id*. at 12); and

- Opinions based on a 2010 PowerPoint presentation that Ethicon knew, but did not warn, of the risk of "nerve entrapment, nerve tethering, and nerve severing" (*id*.).

This Court has repeatedly held that it will not permit expert testimony on "Ethicon's knowledge, state of mind, or other matters related to corporate conduct and ethics" because these matters "are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 186872, at *6 (S.D.W. Va. Jan. 15, 2014) (citing cases); *see also, e.g.*, *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703 (S.D.W. Va. 2014); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D.W. Va. 2013); *Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *3-4 (S.D.W. Va. Feb. 7, 2015). The Court has also excluded opinions that offer "simply a narrative review of corporate documents" because these "opinions" are not helpful to the jury. *Huskey*, 29 F. Supp. 3d at 706; *see also Edwards*, 2014 WL 3361923, at *3, 10 (finding expert's explanation of company documents not helpful and noting thatthe jury is capable of reading and interpreting the documents itself); *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *32 (S.D.W. Va. Sept. 29, 2014) (same).

As in these cases, the jury here is equally capable of reading and interpreting company documents and drawing its own conclusions without the assistance of expert testimony. Any statements of corporate conduct, knowledge, and motives are not helpful to the jury and do not survive Rule 403 balancing. They should be excluded in their entirety.

II. Dr. Veronikis's Opinion that TVT Is Not Suitable for Its Intended Application Because It Degrades, Frays, and Experiences Particle Loss Is Not the Product of a Reliable Methodology.

Dr. Veronikis's defective-design opinions are anchored in his belief that TVT mesh frays, degrades, and experiences particle loss after implantation, which render it unsuitable for use in treating SUI. Ex. C, Veronikis TVT Report at 5, 9-10. This opinion is not the result of a reliable methodology for two reasons.

First, Dr. Veronikis made clear that, at its core, his opinion about fraying, degradation, and particle loss is based on nothing more than internal Ethicon corporate documents, which are not themselves a reliable basis for an expert's opinion:

> Q. Have you read any study that the TVT® mesh falling apart, pieces coming off it, have been a clinical problem for anyone?
>
> A. I've read in the Ethicon documents that people complained that it was fraying.
>
> Q. Have you read any published scientific literature where fraying and the TVT® mesh falling apart was recognized to be a problem?
>
> A. Not yet.

Ex. E, Veronikis 4/30/16 Dep. Tr. 72:20-73:7. As explained, this Court has repeatedly excluded opinions that offer "simply a narrative review of corporate documents" because these "opinions" are not helpful to the jury. *Huskey*, 29 F. Supp. 3d at 706; *see also Sanchez*, 2014 WL 4851989, at *32; *Edwards*, 2014 WL 3361923, at *10. But a "narrative review of corporate documents" is all that undergirds Dr. Veronikis's opinion that the TVT frays, degrades, and loses particles.

Second, even though Dr. Veronikis later claims to rely on the Clavé study, which he claims "says that degradation of TVT® polypropylene produces clinical problems" (Ex. E, Veronikis 4/30/16 Dep. Tr. 98:4-8), Dr. Veronikis admits that he did not cite this study *or*

discuss it as the basis for any opinion expressed in the body of the report (*id*. at 294:22-295:13). Even so, the footnote reference is merely mentioned as part of Dr. Veronikis's narrative history of Ethicon internal company documents as to what Ethicon "knew." Ex. C, Veronikis TVT Report at 12 n.29; Ex. D, Veronikis Gynemesh PS Report at 6 n.3. It is cited for nothing more. Without any support for his opinion, it is merely *ipse dixit* and excludible on that basis. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 603 (excluding general-causation testimony offered by expert as inadmissible *ipse dixit* where the expert failed to identify any supporting basis for the opinion, including scientific literature).

III. Dr. Veronikis's Criticism of Ethicon's Recommended Surgical Technique and Instrumentation Should Be Excluded as Irrelevant.

Although he never mentioned any such opinion in his Rule 26 expert report, Dr. Veronikis testified that aspects of the *surgical technique* Ethicon recommends for TVT render it "unsafe" and unsuitable for use. Ex. E, Veronikis 4/30/16 Dep. Tr. 21:10-24:3. He emphasized that his criticism of the technique is inseparable from his criticism of the TVT mesh design, specifically: "I have criticism of both. I don't know which one would be more because they're sort of together. You really can't isolate the one from the other." *Id.* at 27:16-19. This new, previously undisclosed opinion should be excluded for Dr. Veronikis's failure to comply with Rule 26 (*see In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 644 (new opinion not discussed in a Rule 26 expert report or supplemental report excluded)), but is independently inadmissible because it is irrelevant to Plaintiffs' design-defect claims.

Simply, criticism of surgical technique cannot support a claim that an implantable medical device is defectively designed. *Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999) (rejecting plaintiff's theory that defendant's spinal-fixation device was defective because there were alternative spinal-fusion procedures available that did not use spinal-fixation devices);

Bogle v. Sofamor Danek Grp., Inc., No. 95-8646, 1999 WL 1132313, at *4 (S.D. Fla. Apr. 9, 1999) (emphasizing that the expert's "testimony fails to identify any particular defect *with the product*. He testified that the design of the screw made it difficult to utilize, that only the most skilled surgeons could implant it with any degree of success, that if he were designing a pedicle screw he would design it differently . . . . The Court is not persuaded that such testimony identifies a defect in the product, rather, at the most it identifies that it is a product reserved to a top-rate surgeon" (emphasis added)); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 256 (E.D.N.Y. 1999) (granting summary judgment on design-defect claim where expert focused on surgical technique and non-instrumental spinal repair, not a defect in the product itself); *Schmidt v. C.R. Bard, Inc.*, No. 2:11-cv-00978, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) (granting summary judgment to defendant because "[t]he fact that an alternative method of surgical hernia repair was potentially available does not support Plaintiff's design defect claim").

To the extent that Dr. Veronikis's design-defect opinion is premised on criticism of the TVT surgical technique, that opinion is not relevant to prove design defect because a surgical technique is not a product.

IV. Dr. Veronikis's Opinion that Polypropylene Mesh Is Defective When Used Transvaginally to Treat Stress Urinary Incontinence Is Unreliable Because It Is Inconsistent with His Clinical Practice.

Dr. Veronikis proposes to testify that the "benefits of the TVT are outweighed by the serious complications associated with the device" and that, consequently, the product "is not suitable for its intended application." Ex. C, Veronikis TVT Report at 5, 8. His deposition testimony, however, confirms that Dr. Veronikis's opinions are not limited to just TVT, but that he views *all* polypropylene mesh slings as inherently unsafe for treatment of SUI:

> Q. So is it fair to say that all of the meshes that are on the market today, you consider all of them for SUI surgery to be unsafe?

A. At this point in time with everything I've reviewed and everything I've learned, they are not safe.

Q. Okay. None of them?

A. None of them.

Ex. E, Veronikis 4/30/16 Dep. Tr. 144:10-18.

But Dr. Veronikis's sweeping condemnation of polypropylene mesh in this litigation cannot be squared with his ongoing clinical practice. He freely concedes that he still uses polypropylene mesh slings today. Specifically, he has been using a polypropylene sling manufactured by Caldera, called "Desara," since 2010 to treat patients with SUI. *Id*. at 27:20-28:10. He should not be permitted to offer a litigation-driven opinion that use of polypropylene mesh is unsafe when that opinion is contrary to what he advocates for the patients he treats in his clinical practice—*i.e*., that the use polypropylene mesh is safe.

Ethicon acknowledges that this Court has noted that "an expert's formulation of his or her opinion for the purposes of litigation does not, by itself, justify the expert's exclusion." *Sanchez*, 2014 WL 4851989, at *4. The court cautioned, however, that this concern "does have a role in applying *Daubert*" in that the court considers "'[w]hether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying.'" *Id.* (quoting *Hoffman v. Monsanto Co.*, No. 2:05-CV-00418, 2007 WL 2984692, at *3 (S.D.W. Va. Oct. 11, 2007)). The court concluded that it "will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable," but "will consider the independence of an expert's testimony as evidence that his 'research comports with the dictates of good science.'" *Id.* (quoting *Daubert v. Merrell Dow Pharm., Inc.* ("*Daubert II*"), 43 F.3d 1311, 1317 (9th Cir. 1995)).

Dr. Veronikis's opinion that *no* polypropylene mesh is safe for SUI surgery is not specific to TVT. And yet Dr. Veronikis testified that he continued to use—*and still uses*—polypropylene slings to treat SUI well after he began offering his expert opinions. This double standard—one for this litigation and one for his own practice—undermines the reliability of his opinions. As *Daubert* and this Court have made clear, an expert must "' employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field . . . .'" *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 675 (S.D.W. Va. 2014) (quoting *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001)); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (instructing that an expert must employ in the courtroom "the same level of intellectual rigor that characterizes the practice of an expert" in the expert's field).

When the expert employs one standard for a courtroom and another standard for his everyday practice, the standard he crafted just for the courtroom is excludable under *Daubert*. *See Mathison v. Boston Scientific Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *10 (S.D.W. Va. May 6, 2015) (excluding Dr. Blavias's safety opinion because he "'phrase[s] [his] words differently in the peer-reviewed literature than [he] do[es] in the legal literature because it's two different sets of rules'"). Therefore Dr. Veronikis's continued use of a polypropylene mesh product in his clinical practice shows that his opinion that *all* polypropylene mesh is unsafe for SUI surgery lacks the intellectual rigor required by *Daubert* and its progeny, and is instead an opinion that has been crafted solely for this litigation. It should be excluded.

V. Pronova Is Not a *Feasible* Alternative Design Because Dr. Veronikis Concedes It Is Not Available for and Has Not Been Studied for Prolapse Repair.

During his deposition, Dr. Veronikis opined for the first time that there is an alternative mesh design, called Pronova, which he believes would be safe for use in prolapse repair. Ex. E,

Veronikis 4/30/16 Dep. Tr. 238:1-239:7. This is a new opinion, which was never expressed in his Rule 26 expert reports, and should be excluded for that reason, alone. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 644. Apart from that omission, however, Dr. Veronikis's opinion about Pronova is also inadmissible because it is—by his own admission—based on nothing more than internal company documents that Dr. Veronikis saw during his preparation for this case. Ex. E, Veronikis 4/30/16 Dep. Tr. 238:1-4, 239:21-240:12. Indeed, Dr. Veronikis admits there has been no peer-reviewed literature to determine whether Pronova can be used for prolapse repair. *Id.* 240:13-16.

But more importantly, Dr. Veronikis's new opinion regarding Pronova has no bearing on whether it is a *feasible* alternative design for prolapse repair because he agreed it is not available for use in prolapse repair. When asked whether "there's any safe alternative for the use of mesh . . . for prolapse" during his deposition, Dr. Veronikis testified "[n]ot the current mesh that we have." *Id.* at 237:13-20. He further conceded that Pronova has not even been used for prolapse repair in studies. *Id.* at 239:1-3. As such, he cannot—consistent with *Daubert*—opine regarding Pronova's suitability as an alternative product for prolapse repair.

VI. The Court Should Preclude Dr. Veronikis from Testifying Regarding the Impermissible Legal Conclusions Made in His Expert Reports.

This Court has made clear on numerous occasions that drawing legal conclusions is within the province of the jury, not the subject of expert testimony. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 629; *see also Eghnayem*, 57 F. Supp. 3d at 691 ("In the Fourth Circuit, 'opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.'" (quoting *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006)).

Despite this well-established rule of law, Dr. Veronikis seeks to offer the following legal conclusions:

- The TVT mesh "is not suitable for its intended application" (Ex. C, Veronikis TVT Report at 5);

- "Ethicon failed to adequately describe, inform or explain to physicians how to properly 'tension' the TVT" (*id.*);
- Ethicon's "Instructions for Use ("IFU") are inadequate based on Ethicon['s] failure to include warnings about the adverse reactions and risks . . . ." (*id.*);
- TVT "is defectively designed" because "[a]ny benefits that Ethicon believes are attributable to the TVT are outweighed by the risks of the device" (*id.* at 7-8);
- "Ethicon failed to adequately warn physicians and patients about known problems with the TVT" (*id.* at 10);
- "Ethicon failed to warn about the risk of stiffness and resulting pain associated with the laser cut TVT mesh" (*id.* at 14);
- "Ethicon failed to warn about the difficulty of removing the TVT mesh in its entirety once it is implanted" (*id.* at 14);
- "Ethicon failed to warn physicians and patients about the risks associated with the Gynemesh PS . . . ." (Ex. D, Veronikis Gynemesh PS Report at 10);
- "Ethicon failed to adequately convey any warning to doctors regarding . . . adverse study results" (*id.* at 15);
- "Gynemesh PS should not have been considered reasonably safe for repair of pelvic organ prolapse" (*id.*); and
- "[T]he risks of Gynemesh PS for transvaginal pelvic organ prolapse repair far outweighed any claimed benefits, and the implantation of this product resulted in unacceptable rates of" mesh-related injuries (*id.* at 23).

Consistent with this Court's earlier rulings, Dr. Veronikis should be precluded from offering these legal conclusions.

VII. Dr. Veronikis's Opinions on Ethicon's Intentions and Narrative Review of Corporate Documents Are Inadmissible.

In addition to Dr. Veronikis's repeated use of internal Ethicon documents to root his warnings opinions in Ethicon's alleged corporate knowledge, he also seeks to use internal company documents to suggest that Ethicon intentionally deceived and put at risk patients and

members of the medical community. As explained, this Court has repeatedly excluded testimony based on "Ethicon's knowledge, state of mind, or other matters related to corporate conduct and ethics" because they "are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *Lewis*, 2014 WL 186872, at *6; *see also Wise*, 2015 WL 521202, at *3-4; *Huskey*, 29 F. Supp. 3d at 703. Consistent with those rulings, Dr. Veronikis's corporate-motive opinions should be excluded in their entirely, including (but not limited to) the following opinions:

- Opinion that Ethicon's IFU was "intentionally misleading" because "Ethicon carried out no tests or studies" to back up statements made within the IFU (Ex. D, Veronikis Gynemesh PS Report at 9);
- Opinion that Ethicon would be "needlessly endangering" its patients if it did not warn in the IFU of "a portion of the population not listed which would be subject to additional risks" (*id.* at 16); and
- Opinion that "Ethicon's documents reflect an intent to 'differentiate'" study results that were purportedly not supportive of "the clinical safety of the Prolift kit" (*id.* at 21).

CONCLUSION

For these reasons, Ethicon asks this Court to grant its Motion to Exclude the General-Causation Testimony of Dionysios K. Veronikis, M.D.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 23, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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